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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Ezio Bombardelli

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EXAMINER

MI, QIUWEN

ART UNIT

PAPER NUMBER

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/580,190	Applicant(s) BOMBARDELLI, EZIO	
	Examiner QIUWEN MI	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 02 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 6-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 6-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's reply and declaration filed on 4/2/08 are acknowledged.

The objection over claim 15, and the 102, 103 rejections over Korneyev, as evidenced by Zulli et al and Ghosal are hereby withdrawn due to Applicant's convincing argument.

Claims Pending

Claims 3-5 are cancelled. Claims 1, 2, and 6-23 are pending. Claims 1, 2, and 6-23 are examined on the merits.

Claim Rejections –35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6, 15, and 17 remain rejected under 35 USC § 102 (b) as being anticipated by Yaloveny Agric Ind (SU 1373398A), as evidenced by Nieuwenhuizen et al (US 2003/0064937)*, and Cooper et al (US 6,379,720)*.

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 1/2/2008, repeated below. Applicants' arguments filed have been fully considered but they are not deemed to be persuasive.

Yaloveny Agric Ind teaches a composition comprising grapes and extract of hops (see Abstract)

As evidenced by Nieuwenhuizen et al (US 2003/0064937), grape contains procyanidins [0023, 0077].

As evidenced by Cooper et al, hops (the same as *Humulus lupulus*, col 1, lines 50-55) extract contains alpha acids (phloroglucinols), represented by humulone and its congeners (columulone, admululone) and beta acids, represented by lupulone and its congeners (colupulone, adlupulone) (col 1, lines 50-58).

Therefore, the reference is deemed to anticipate the instant claim above.

Applicant argues that “Yaloveny Agric Ind fails to disclose compositions for treatment of affections of the oral cavity and upper respiratory tract, such as are set forth in claims 1 and 15. The soft drinks of Yaloveny Agric Ind also represent non-analogous art (page 6, 1st paragraph).

The intended use of the composition was analyzed for patentable weight. It is deemed that the preamble ‘breathes life’ into the claims in that the prior art product must not be precluded for use to treat affections of the oral cavity and upper respiratory tract. It is deemed that the composition disclosed by the cited reference is not precluded for carrying out the intended function of the claims.

Arguments that the alleged anticipatory prior art is nonanalogous art or teaches away from the invention’ or is not recognized as solving the problem solved by the claimed invention, [are] not germane’ to a rejection under section 102.” *Twin Disc, Inc. v.*

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United States, 231 USPQ 417, 424 (Cl. Ct. 1986) (quoting *In re Self*, 671 F.2d 1344, 213 USPQ 1, 7 (CCPA 1982)). See also *State Contracting & Eng'g Corp. v. Condotte America, Inc.*, 346 F.3d 1057, 1068, 68 USPQ2d 1481, 1488 (Fed. Cir. 2003).

Claim Rejections –35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 7, 8, 15, 16, 18, and 19 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Yaloveny Agric Ind (SU 1373398A), as evidenced by Nieuwenhuizen et al (US 2003/0064937)*, and Cooper et al (US 6,379,720)*.

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 1/2/2008, repeated below. Applicants' arguments filed have been fully considered but they are not deemed to be persuasive.

Yaloveny Agric Ind teaches a composition comprising grapes and extract of hops (see Abstract)

As evidenced by Nieuwenhuizen et al (US 2003/0064937), grape contains procyanidins [0023, 0077].

As evidenced by Cooper et al, hops (the same as *Humulus lupulus*, col 1, lines 50-55) extract contains alpha acids (phloroglucinols), represented by humulone and its congeners (cohumulone, admululone) and beta acids, represented by lupulone and its congeners (colupulone, adlupulone) (col 1, lines 50-58).

Yaloveny Agric Ind does not teach the claimed amount of the components in the composition.

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the invention of Yaloveny Agric Ind since the composition of Yaloveny Agric Ind yielded beneficial results in food industry, one of ordinary skill in the art would have been motivated to make the modifications. The result-effective adjustment in conventional working parameters (e.g., determining an appropriate amount of the components within the composition) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Claims 1, 2, and 6-23 remain rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Walker et al (US 5,474,774), Imaoka et al (JP 406179609), Barney et al (US 5,370,863), Van den Berghe (US 6,284,289), and Zou (CN 1421240), as evidenced by Gorenbein et al (US 5,955,102)*, Nieuwenhuizen et al (US 2003/0064937)*, Cooper et al (US 6,379,720)*, Ghosal (US 6,224,906)*, and Giovanni et al (Oligomeric acylphloroglucinols from myrtle (*Myrtle communis*), Journal of Natural Products, 65 (3): 334-8, 2002)*.

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 1/2/2008, repeated below. Applicants' arguments filed have been fully considered but they are not deemed to be persuasive.

Walker et al teach a composition for inhibiting the adhesion of *E. coli* bacteria to surfaces in a mammalian oral cavity (thus administering to a patient) (claim 1). Walker et al also teach that the invention comprises an extract made from plant material of plant species of the genus *Vaccinium*, and which is significantly enriched for an activity that interferes with adhesion of bacterial cells to surfaces (col 1, lines 42-46). Walker et al further teach that *V. myrtillis* (bilberry), etc are useful species (col 1, lines 63-67).

As evidenced by Gorenbein et al, bilberry extract (the same as *Vaccinium myrtillus*, col 3, lines 10-15) contains anthocyanoside.

Imaoka et al teach a composition with high antibacterial activity on oral bacteria (thus administering to a patient) comprising grape extract.

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As evidenced by Nieuwenhuizen et al (US 2003/0064937), grape contains procyanidins [0023, 0077].

Barney et al teach a composition for inhibiting undesirable gram positive microorganisms in the oral cavity bacteria proliferation (thus administering to a patient) comprising hops acids (col 1, lines 5-10).

As evidenced by Cooper et al, hops (the same as *Humulus lupulus*, col 1, lines 50-55) extract contains alpha acids (phloroglucinols), represented by humulone and its congeners (cohumulone, admululone) and beta acids, represented by lupulone and its congeners (colupulone, adlupulone) (col 1, lines 50-58).

Van den Berghe teaches a composition for treating cold sores (infection in oral cavity) (thus administering to a patient) comprising *Myrtus communis* and *Hypericum perforatum* (col 4, lines 14-22).

As evidenced by Ghosal, St. John's Wort extract (the same as *Hypericum perforatum*, col 1, lines 10-15) contains phloroglucinols and procyanidins (cols 2&3, Table 1).

As evidenced by Giovanni et al, *Myrtus communis* contains phloroglucinols (see Abstract).

Zou teaches a composition for treating sore and swelling throat, acute pharyngitis, and acute laryngitis (oral cavity infection) (thus administering to a patient) comprising mint oil (see Abstract).

"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose ...[T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.).

In the instant case, all of the above-listed ingredients were known for oral cavity infection. Thus, one of ordinary skill in the art would have had a reasonable expectation that the combination of these compounds would have been additively beneficial in treating any inflammatory condition including brain inflammation in multiple sclerosis patients.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for oral cavity infection. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, In re Sussman, 1943 C.D. 518.

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. Although the prior art did not specifically disclose the amounts of each constituent as in the claims, it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentration is an art-recognized result-effective variable which would have been routinely determined and optimized in the pharmaceutical art.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to combine the inventions of Walker et al, Imaoka et al, Barney et al, Van den Berghe, and Zou since all of them teach compositions for oral cavity infection individually in the art. Since all the compositions yielded beneficial results in for oral cavity infection, one of ordinary skill in the art would have been motivated to make the modifications. The result-effective adjustment in conventional working parameters (e.g., determining an appropriate amount of the components within the composition) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Claim 11 is a product-by-process claim. It is deemed that the product disclosed by Van den Berghe is not materially differently from the claimed *Myrtus communis* extract, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

*This reference is cited merely to relay an intrinsic property and is not used in the basis for rejection *per se*.

Applicant argues that Cooper et al fail to mention phloroglucinol (page 6, 3rd paragraph; page 8, 2nd paragraph).

Cooper et al teach humulone and colupulone, and they are all phloroglucinol, as evidenced by claim 7.

Applicant argues that YALOVENY AGRIC IND, N!EUWENHUIZEN et al. and COOPER et al., and Walker et al fail to disclose compositions for treatment of affections of the oral cavity and upper respiratory tract, such as are set forth in claims 1 and 15 of the present invention (page 6, 4th paragraph; page 7, 2nd paragraph;).

As indicated above, the intended use of the composition was analyzed for patentable weight. It is deemed that the preamble ‘breathes life’ into the claims in that the prior art product must not be precluded for use to treat affections of the oral cavity and upper respiratory tract. It

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is deemed that the composition disclosed by the cited references is not precluded for carrying out the intended function of the claims.

Applicant argues that adhesion inhibitors of Walker et al represent non-analogous art (page 7, 2nd paragraph).

In response to applicant's argument about nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, all references are combined for their antibacterial activities, and adhesion inhibition is relevant to the intended use of the claims, which is to treat affections of oral activity and upper respiratory tract, thus the art is pertinent.

Applicant argues that Barney et al fail to teach or suggest the utilization of pure phloroglucinols from *Humulus* extract, and fail to teach or suggest combining hops acids with other ingredients (page 7, last paragraph).

This is not found persuasive. It would be obvious for one of the ordinary skills in the art to use the pure phloroglucinols from *Humulus* extract to enhance the inhibition to the undesirable gram positive microorganisms in the oral cavity.

Applicant argues that Barney et al fail to teach or suggest combining hops acids with other ingredients (page 7, last paragraph). Applicant also argues that there is no hint in Van de Berghe that would have led a skilled person to select two specific ingredients to combine with procyanidins or *Camillia sinensis* extract (page 8, 3rd paragraph).

Applicant argues that there is no specific suggestion or teaching in the references to combine prior art. All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of invention. In addition, KSR forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding of obviousness. See the recent Board decision *Ex parte Smith*, -- USPQ2d--, slip op. at 20 (Bd. Pat. App. & Interf. June 25, 2007) (citing KSR, 82 USPQ2d at 1396) (available at <http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf>).

Applicant argues that one skilled in the art would not have chosen colupolone from Barney et al as it is less active than the other tested acids. Applicant further argues that Barney et al teach away from the present invention (page 7, last paragraph bridging page 8).

Applicant argues that the cited reference teaches away from the claimed invention. According to MPEP 2123, "Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same

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use.” *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). Furthermore, “[t]he prior art’s mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed....” *In re Fulton*, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004).

Applicant argues that mint oil is not contained in the composition of the present invention, thus Zou is non-analogous art (page 8, 4th paragraph).

This is not true, as mint oil is required in the composition in claim 14.

Applicant argues that the multiplicity of references could only be combined via impermissible hindsight (page 9, 3rd paragraph).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

The declaration under 37 CFR 1.132 filed on 4/2/08 is insufficient to overcome the rejection over two independent claims 1 and 15 as set forth in the last Office action because: The independent claims 1 and 15 are rejected under 102 over Yaloveny Agric Ind.

Applicant's arguments have been fully considered but they are not persuasive, and therefore the rejections in the record are maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

QM

/Christopher R. Tate/
Primary Examiner, Art Unit 1655